

JET/CDM/NSG/DBL: January 2017
(by information)

**IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ALABAMA
JASPER DIVISION**

UNITED STATES OF AMERICA)
)
)
v.) **Case No. _____**
)
CHRISTOPHER NUÑEZ)
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)
)
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INFORMATION

The United States Attorney charges that:

At all times relevant to this Information:

INTRODUCTION

I. PHARMACEUTICAL SERVICES

1. Pharmacies may dispense pre-manufactured and traditionally compounded (hereafter “compounded”) medications.
2. A pre-manufactured medication is mass-produced for use by a large population of patients. A pre-manufactured medication is purchased by a pharmacy in the same form in which the pharmacy dispenses it to patients. Pre-manufactured medications include prescription topical products, pain patches, and pain sprays.
3. Compounded medications are a customized combination of medicines initiated and prescribed by a licensed prescriber based upon the prescriber-patient

relationship and taking into consideration the particular patient's diagnoses, medical condition, individual health factors, and reaction to other medications. A licensed prescriber issues a prescription for these medications after determining that commercially available medications are not as beneficial or may be inappropriate and/or harmful to the patient. The ingredients of such compounded medication are mixed together by the compounder in the exact strength and dosage required by an individual patient.

4. The U.S. Food and Drug Administration ("FDA") offers the following examples of when drugs would be compounded: **(a)** if a patient has an allergy and needs a medication to be made without a certain dye preservative; and **(b)** if an elderly patient or child cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available.

5. Due to the unique and individualized nature of compounded medications, such medications are neither commercially available nor distributed in mass quantities.

6. Because compounded pharmaceuticals are custom made to fit the unique needs of each patient, the FDA does not pre-approve compounded medications and therefore does not verify the safety or effectiveness of compounded drugs prior to dispensing. In Alabama, the Alabama Board of Pharmacy regulates

the practice of pharmacy, including traditional pharmacy compounding.

II. PRIVATE AND GOVERNMENT INSURANCE PLANS

7. Various entities, government and private, offer prescription drug benefits as part of health insurance plans. A beneficiary in such an insurance plan can fill a prescription at a pharmacy and use her or his plan to pay for some or all of the prescription.

8. Blue Cross Blue Shield of Alabama (“BCBSAL”) was a private insurance company providing medical and drug insurance coverage in Alabama and elsewhere.

9. The Medicare Program (“Medicare”) is a federally funded program that provides free or below-cost health care benefits to certain individuals, primarily the elderly, blind, and disabled. Medicare programs covering different types of benefits are separated into different program “parts.” Part D of the Medicare, Improvement, and Modernization Act of 2003 subsidizes the costs of certain prescription drugs, including certain compounded drugs, for Medicare beneficiaries in the United States.

10. TRICARE is a health care program of the United States Department of Defense (“DOD”) Military Health System that provides coverage for DOD beneficiaries worldwide, including active duty service members, National Guard and Reserve members, retirees, their families, and survivors. TRICARE provides

coverage for certain prescription drugs, including certain compounded drugs.

11. BCBSAL, Medicare, and TRICARE are “health care benefit programs” as that term is defined by Title 18, United States Code, Section 24(b), and used in Title 18, United States Code, Section 1347.

III. THIRD PARTY ADMINISTRATORS

12. A Pharmacy Benefit Manager (“PBM”) is a third party administrator of prescription drug programs, including privately or government insured drug plans, and acts on behalf of one or more prescription drug plans.

13. A Pharmacy Services Administrative Organization (“PSAO”) is also a third party entity, which provides various services such as contract negotiation and communication to pharmacies. Pharmacies may contract with PSAOs, which in turn contract with PBMs, such that PSAO member pharmacies may participate in a PBM network.

14. A pharmacy could participate in a privately or government insured plan directly by entering an agreement with the insured plan, or indirectly by joining a PBM’s pharmacy network through an agreement with a PBM or a PSAO.

15. Prime Therapeutics (hereafter, “Prime”) is a PBM for BCBSAL and other insurance plans.

16. Prime is a “health care benefit program,” as defined by Title 18, United

States Code, Section 24(b), and as that term is used in Title 18, United States Code, Section 1347.

17. AmerisourceBergen Elevate Provider Network (formerly Good Neighbor Pharmacy Provider Network) (hereafter, “Good Neighbor”) and others are PSAOs through which pharmacies could enter PBMs’ pharmacy networks.

18. To become a PBM network pharmacy, a pharmacy agrees to be bound by, and comply with, all applicable State and Federal laws, specifically including those addressing fraud, waste, and abuse. A pharmacy also agrees to be bound by the PBM’s rules and regulations. These rules include prohibitions against fraudulent conduct, including submitting claims for invalid prescriptions, submitting claims in a way that bypasses PBM billing safeguards, paying kickbacks, and waiving patient co-pays. PBMs require pharmacies to collect co-pays, typically a fixed amount, from patients, in part so that the patient has “skin in the game” and is motivated to decline medically unnecessary or otherwise fraudulent prescriptions.

19. When a pharmacy receives a prescription from a privately or government insured beneficiary, the pharmacy is to collect any applicable co-pay from the beneficiary, dispense the drug to the beneficiary, and submit a claim for reimbursement to the PBM that represents the beneficiary’s insured drug plan. The pharmacy periodically receives payment for submitted claims from the Plan, PBM,

or a PSAO. If payment is made by a PBM or PSAO, those entities are ultimately reimbursed, directly or indirectly, by the insured plan.

IV. THE DEFENDANT, CO-CONSPIRATORS, & PHARMACIES

20. Northside Pharmacy d/b/a Global Compounding Pharmacy (hereafter, “Global”) was an Alabama company that provided pharmaceutical services. It operated from two locations. It compounded and shipped its pre-manufactured and compounded products from its pharmacy location, 922 20th Street, Haleyville, Alabama. It processed prescriptions, including initial receipt, billing, and patient contact, from its billing center located at 4700 140th Avenue North, Suites 111 and 112, Clearwater, Florida. The billing center was referred to as the “Clearwater Call Center.”

21. Global employed pharmacists, pharmacy technicians, and other employees who worked from Global in Haleyville, Alabama. Additionally, Global hired outside sales representatives, who worked from various locations throughout the United States, were primarily responsible for generating prescriptions from licensed prescribers, and reported to regional district managers. Global also hired inside sales representatives, sometimes also referred to as “pharmacy technicians,” who worked at the Clearwater Call Center, and who were generally responsible for billing and patient contact.

22. The following were among the individuals who worked at Global:
23. **MANAGEMENT PERSON #1** was an owner, President, and Chief Executive Officer of Global.
24. **MANAGEMENT PERSON #2** was an owner, Vice President, and Chief Operating Officer of Global. **MANAGEMENT PERSON #2** resigned from Global on or about July 21, 2015.
25. **MANAGEMENT PERSON #3** was Global's Regional Sales Director, then National Sales Director and Vice President of Sales. District managers, who supervised outside sales representatives, reported to **MANAGEMENT PERSON #3**.
26. **MANAGEMENT PERSON #4** was Global's Inside Sales Manager, and supervised the inside sales representatives at the Clearwater Call Center.
27. **OUTSIDE SALES REPRESENTATIVE #3** was an outside sales representative for the Alabama region.
28. Defendant **CHRISTOPHER NUÑEZ** was an inside sales representative for Global. From in or about September 2014 to at least in or about June 2016, he was an inside sales representative for Global, and was located in Clearwater, Florida. As an inside sales representative, his responsibilities included patient contact and billing. Global paid defendant **NUÑEZ** a base salary and 1%

commission for each prescription he processed. On or about July 30, 2015, defendant **NUÑEZ** became a licensed pharmacy technician in Florida. On or about November 16, 2015, defendant **NUÑEZ** became a licensed pharmacy technician in Alabama.

29. **MANAGEMENT PERSON #1** and other co-conspirators caused Global to engage with multiple affiliate pharmacies, which Global managers used to fill and bill for prescriptions when Global could not bill for them directly. One such affiliate was Carrollton Pharmacy d/b/a The Prescription Shop (“TPS”), located at 41254 Highway 195, Haleyville, Alabama. In or about August 2015, **MANAGEMENT PERSON #1** and other co-conspirators caused TPS to obtain Prime coverage and caused Global to begin transferring prescriptions for Prime beneficiaries to TPS. The decision to transfer these prescriptions occurred after **MANAGEMENT PERSON #1** and other co-conspirators were informed on or about May 29, 2015 by Prime that Global would be terminated from the Prime network effective September 4, 2015 for failing to comply with Prime’s terms and conditions. At **MANAGEMENT PERSON #1**’s direction, two Global employees became the listed owners of TPS, thus concealing Global and **MANAGEMENT PERSON #1**’s involvement in TPS’s operations from Prime. TPS operated using many of Global’s processes and employees.

30. **MANAGEMENT PERSON #1** and other co-conspirators caused Global and TPS to contract with BCBSAL to provide health insurance to employees and their dependents, who were located in Alabama and elsewhere in the United States.

31. **MANAGEMENT PERSON #1** and other co-conspirators caused Global and TPS to contract, including through PSAs, to participate in the pharmacy networks of various PBMs, including Prime. Global billed for prescription drugs through its contracts with these PBMs and PSAs.

Count One
Conspiracy
18 U.S.C. § 371

32. Paragraphs 1 to 31 of the Introduction of this Information are fully incorporated as though set forth herein.

THE CONSPIRACY

33. From in or about September 2014, and continuing until at least in or about June 2016, the exact dates being unknown, within Winston County in the Northern District of Alabama, and elsewhere, defendant

CHRISTOPHER NUÑEZ,

knowingly and willfully conspired, combined, and agreed with others known and unknown to the United States:

- a. to execute a scheme and artifice to defraud health care benefit programs, as defined in Title 18, United States Code, Section 24(b), that is, BCBSAL, Medicare, TRICARE, Prime, and others, and to obtain, by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of, said health care benefit programs, in connection with the delivery and payment for health care benefits, items and services, in violation Title 18, United States Code, Section 1347;
- b. to devise and intend to devise a scheme and artifice to defraud BCBSAL, Medicare, TRICARE, Prime, and others and to obtain money and property belonging to others by means of materially false and fraudulent pretenses, representations, and promises by use of interstate wire transmissions, in violation of Title 18, United States Code, Section 1343; and
- c. to devise and intend to devise a scheme and artifice to defraud BCBSAL, Medicare, TRICARE, Prime, and others and to obtain money and property belonging to others by means of materially false and fraudulent pretenses, representations, and promises, by use of United States mail and private and commercial interstate carrier, in violation of Title 18 United States Code, Section 1341.

MANNER AND MEANS OF THE CONSPIRACY

34. It was a part of the conspiracy that to generate sales, **MANAGEMENT PERSON #1** and others sought out and hired as outside sales representatives, individuals: **(a)** with marital and other close familial relationships to individuals with prescribing authority, including physicians, physician assistants and nurse practitioners, (hereafter “Prescribers”) and **(b)** who were Prescribers or worked in Prescribers’ offices.

35. It was a further part of the conspiracy that to generate sales, **MANAGEMENT PERSON #1** and other co-conspirators directed and encouraged Global outside sales representatives to work, typically without pay, in Prescribers' offices, including by reviewing patient files and pushing and promoting Global's products to the Prescribers' patients.

36. It was a further part of the conspiracy that **MANAGEMENT PERSON #3** and other co-conspirators regularly instructed Global employees to obtain prescriptions for Global's highest reimbursing products for themselves and their family members regardless of medical necessity.

37. It was a further part of the conspiracy that some of these high reimbursing prescription drugs included:

- a. Active Prep Kit II ("APK II"), described in marketing materials as an in-office compounding kit for anti-inflammatory and analgesic treatment, for pain relief from musculoskeletal conditions, arthritis and neuropathy.
- b. Lidocin, described in marketing materials circulated by Global as a topical analgesic that "provides a powerful formulation for pain control and is helpful for relief of pain associated with cuts, scrapes, and minor skin irritations."
- c. Silapak, also referred to as PharmaPak, a product Global's marketing flyer described as a "topical Skin Repair Complex . . . designed to provide relief for irritating skin conditions caused by numerous etiologies such as eczema, allergic reactions, irritating keloid and hypertrophic scars, psoriasis, and allergic reactions."

The flyer further stated that “Silapak is not indicated for pregnant women or children.”

- d. Medi-Derm Rx, a pain cream, described in Global’s marketing flyer as a topical analgesic/topical anesthetic “used for the temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains, sprains, muscle soreness and stiffness.”
- e. Pain sprays including Camphomex and Mentholix.
- f. Ortho D, a product Global’s marketing materials described as “indicated for dietary management of patients with unique nutritional needs requiring increased folate levels, Vitamin D deficiency or are in need of Vitamin D supplementation.”

38. It was a further part of the conspiracy that to incentivize its employees to obtain prescriptions for these high-reimbursing drugs, **MANAGEMENT PERSON #1** and other co-conspirators paid employees a commission of varying percentages for prescriptions they obtained for themselves and their family members.

39. It was a further part of the conspiracy that Global employees sent to Global prescriptions for these high-reimbursing and other medications that were obtained, not to meet their legitimate medical needs, but rather to obtain commission payments on each of those prescriptions and to maximize Global and its affiliate pharmacies’ profits.

40. It was a further part of the conspiracy that defendant **NUÑEZ** and other

co-conspirators would add and delete ingredients from prescribed compounded drugs, add drugs to prescriptions, and substitute a different drug from that listed on the prescription, in order to maximize profit, and not to meet patients' medical needs.

41. It was a further part of the conspiracy that defendant **NUÑEZ** and other co-conspirators would and did automatically refill patient prescriptions, including those of Global employees and their family members, regardless of whether patients needed or requested refills.

42. It was a further part of the conspiracy that to incentivize patients, including employees and their family members to obtain or retain Global's prescription drugs, **MANAGEMENT PERSON #1**, defendant **NUÑEZ**, and other co-conspirators would routinely waive patients' co-pays.

43. It was a further part of the conspiracy that in responding to PBM audits, **MANAGEMENT PERSON #3**, defendant **NUÑEZ** and other co-conspirators provided false and misleading documents and statements to PBMs to conceal Global's fraudulent billing practices, including co-pay waivers and changes made to prescriptions.

44. It was a further part of the conspiracy that **MANAGEMENT PERSON #1** and other co-conspirators used multiple pharmacies to bill for and dispense prescription drugs in order to conceal **MANAGEMENT PERSON #1**'s

and Global's involvement in these pharmacies from PBM's. These affiliate pharmacies included TPS.

45. It was a further part of the conspiracy that Global and TPS employees shipped many of Global and TPS pre-manufactured and compounded drugs from its Haleyville, Alabama location to customers within and outside Alabama via United States Postal Service ("USPS") and private and commercial interstate carriers such as United Parcel Service ("UPS").

46. It was a further part of the conspiracy that Global, TPS and other affiliate pharmacies received payments from Prime and other PBMs for prescriptions. These payments were sometimes made through PSAsOs.

47. It was a further part of the conspiracy that between in or about October 2014, and in or about March 2016, Global and its affiliate pharmacies would and did pay defendant **NUÑEZ** over \$82,000 into his bank account *4113 at Achieva Credit Union. These monies included his base salary and commission payments for prescriptions he processed.

OVERT ACTS

In furtherance of the conspiracy and to achieve the objects thereof, defendant **NUÑEZ** and others known and unknown to the United States committed and caused to be committed the following overt acts, among others, in the Northern District of

Alabama and elsewhere:

48. In or about September 2014, **MANAGEMENT PERSON #4** hired defendant **NUÑEZ** as an inside sales representative. His responsibilities included billing and patient contact.

49. On or about December 15, 2014, **MANAGEMENT PERSON #4** emailed defendant **NUÑEZ** his commission statement for November. It listed a commission payment of approximately \$2,732.63 due to defendant **NUÑEZ**, with an additional \$2,000 for weekend work.

50. On or about April 8, 2015, a PSAO (Good Neighbor) wire transferred approximately \$349,746.38 to Global's First Metro Bank account, which included payments for prescription drug claims submitted by Global to Prime.

51. On or about July 7, 2015, **MANAGEMENT PERSON #3** sent an email to district managers, stating "We are looking at a new product called Pharmapak/[Silapak]. Right now we know it is covered by BCBS of Al, our insurance. The profit on this is \$2700. We need every rep to get a script for themselves for this."

52. On or about July 16, 2015, defendant **NUÑEZ** emailed an outside sales representative in part as follows "We don't know what ESI covers because those are the plans that we transfer to [an affiliate pharmacy] since we are not contracted. Now

here at Global when ingredients are not covered we remove them until we get a paid claim. Unfortunately [the affiliate pharmacy] does not do that.”

53. On or about September 2, 2015, defendant **NUÑEZ** sent an email to an outside sales representative regarding a patient’s co-pay. It stated “We usually don’t collect from MD offices as a professional courtesy but that’s not something I am allowed to say over the phone really.”

54. In or about November 2015, defendant **NUÑEZ** traveled to TPS’s Haleyville, Alabama pharmacy location to assist with billing, including by substituting prescribed low-reimbursing prescribed drugs, with high-reimbursing, but non-prescribed, drugs.

55. On or about December 17, 2015, **MANAGEMENT PERSON #4** emailed the inside sales representatives, including defendant **NUÑEZ**, stating they would not be receiving their commission checks because most of the claims they billed while at TPS had to be reversed, adding “[l]et’s hound [patients], sell medications, maximize claims & make some money!”

All in violation of Title 18, United States Code, Section 371.

NOTICE OF FORFEITURE

1. The allegations in Count One of this Information are hereby re-alleged and incorporated by reference for the purpose of alleging forfeiture pursuant to Title 18, United States Code, Sections 981(a)(1)(C) and 982(a)(7) and Title 28, United States Code, Section 2461(c),
2. Upon conviction of the offense set forth in Count One of this Information, in violation of Title 18, United States Code, Sections 371, 1341, 1343, and 1347, the defendant,

CHRISTOPHER NUÑEZ,

shall forfeit to the United States of America:

- a. Pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c), any property, real or personal, which constitutes or is derived from proceeds traceable to the offenses of wire fraud in, violation of Title 18 United States Code, Section 1343, and mail fraud, in violation of Title 18, United States Code Section 1341; and
- b. Pursuant to Title 18, United States Code, Section 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of

the health care fraud offense, in violation of Title 18, United States Code, Section 1347.

3. The property to be forfeited includes, but is not limited to, **\$82,886.24**, which represents the amount defendant personally obtained, controlled, and benefitted from as a result of his criminal offenses.

4. If any of the property described above, as a result of any act or omission of the defendant:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c).

All pursuant to 18 U.S.C. §§ 981(a)(1)(C) and 982(a)(7) and 28 U.S.C. § 2461(c).

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